

REMARKS

Claims 67-79 are pending in the above-identified application. Claims 70-74 and 76-79 stand withdrawn from consideration as directed to a non-elected invention. Claims 67-69 and 75 are presently being examined.

Claim 67 has been amended herein to clarify that the claimed antimicrobial peptide consists of an amino acid sequence having 13 to 74 amino acids. Claim 67 has further been amended to recite that the antimicrobial peptide includes synthetic analogues of the core sequence. The amendment to claim 67 is supported throughout the specification, for example, at page 42, lines 8-11, and adds no new matter. Applicants respectfully request entry of the amendment.

Rejections under 35 U.S.C. § 112, second paragraph

The rejection of claims 67-69 and 75 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention, respectfully is traversed. Applicants maintain that claims 67-69 and 75 are clear and definite to one possessing the ordinary level of skill in the art in view of the specification.

In the Advisory Action, the Examiner indicates that, had the amendment to "synthetic peptide mimetics" that Applicants proposed in their Response filed April 19, 2004, been entered, the indefiniteness rejection would be maintained "because the specification describes 'synthetic analogs' of synthetic peptides." (Advisory Action, page 2, paragraph #1). Accordingly, Applicants have amended claim 67 to recite antimicrobial peptides and synthetic analogs of the 7 amino acid comprising the core sequence.

The determination of whether a claim is invalid as indefinite “depends on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the specification.” *See N. Am. Vaccine, Inc. v. Am. Cyanamid Co.*, 7 F.3d 1571, 1579 (1993) (citation omitted).

With regard to the phrase “synthetic analogs,” Applicants respectfully submit that this term, viewed by the skilled person in light of the specification and what was known in the art, is sufficiently clear and definite to meet the requirements of paragraph 112. According to the Federal Circuit, “[M]athematical precision is not required--only a reasonable degree of particularity and definiteness.” *Exxon v. US*, 265 F.3d 1371, 1381; 60 U.S.P.Q.2d 1272, 1279 (Fed. Cir. 2001). A reasonable degree of definiteness is provided to the skilled person viewing the phrase “synthetic analogs of said 7 amino acids” by teaching, for example, at page 42, lines 12-21, that the invention peptides can include synthetic analogs and can be conformationally stabilized by replacing selected amino acid in the original peptide with amino acids that restrict the motion of the peptide chain, for example, beta-branched, N-methyl, alpha,beta-dehydro, alpha,alpha-dialkyl and D-amino acids. The specification also teaches that substitutions of D- or other unusual amino acids into the peptide templates can extend the half-life of an invention peptide. The skilled person would have understood with clarity that synthetic analogs of the seven amino acid core sequence can be beta-branched, N-methyl, alpha,beta-dehydro, alpha,alpha-dialkyl and D-amino acids that stabilize the peptide.

Another significant issue with regard to clarity is the knowledge of one skilled in the art when interpreting the patent disclosure. Notably, the Federal Circuit has overturned cases on the indefiniteness issue where the knowledge of one skilled in the art was not taken into account. *See Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 53 U.S.P.Q.2d 1225 (Fed. Cir. 1999). With regard to the art-knowledge, both the

manufacture of peptidomimetics and the scope of the term itself were well known in the art as evidenced by the Exhibits previously submitted by Applicants.

Page 848, right column, final paragraph.

In view of the above, Applicants respectfully submit that the term “synthetic analogs of said 7 amino acids” was well known in the art at the time the subject application was filed such that the skilled person would understand the scope of claim 67 when the claim is read in light of the specification. In view of the amendment and the above remarks, Applicants respectfully request that the Examiner remove the rejection of claims 67-69 and 75 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Rejections under 35 U.S.C. § 102

Applicants respectfully traverse the rejection of claims 67-69 and 75 under 35 U.S.C. § 102(b), as allegedly anticipated by United States Patent No. 5,409,898, to Darveau et al. The Office Action alleges that, since the claim does not define the “mimetics thereof,” any substituted peptide that retains antimicrobial activity would fall within the scope of the claim (Office Action, mailed January 17, 2004, section 4, page 5).

Applicants respectfully disagree that the peptides set forth in the ‘898 patent, which differ from the claimed antimicrobial peptides by having non-identical natural amino acid residues at several positions qualify as mimetics of the claimed peptides. Applicants have amended claim 67 to recite the phrase “synthetic analogs of said 7 amino acids” to clarify that naturally occurring amino acids are not encompassed as mimetics of the invention and that the synthetic analogs refer to monomers of the 7 amino acids that comprise the core sequence.

Accordingly, removal of the rejection of claims 67-69 and 75 under 35 U.S.C. § 102(b), as allegedly anticipated by United States Patent No. 5,409,898, to Darveau et al. respectfully is requested.

Applicants respectfully traverse the rejection of claims 67-69 and 75 under 35 U.S.C. § 102(b), as allegedly anticipated by Kupsch et al., *EMBO J.*, 12(2): 641-650 (1993). The Office Action alleges that claims 67 and 68 are anticipated by the description in Kupsch et al. of a member of the variable opacity (Opa) outer membrane family of proteins that is designated OPA 65 and has 236 amino acids, including the core sequence ARYRKWK.

As set forth above, base claim 67 has been amended herein to clarify that the claimed antimicrobial peptide consists of an amino acid sequence having 13 to 74 amino acids. The Opa 65 peptide has 236 amino acids and, accordingly, does not fall within the scope of claim 67 and cannot anticipate either base claim 67 or dependent claim 68. In the Advisory Action, the Examiner indicates that, if entered, this amendment would overcome the present rejection (Advisory Action, page 2, "continuation of 5.). Accordingly, Applicants respectfully request removal of the rejection of claims 67 and 68 under 35 U.S.C. § 102(b), as allegedly anticipated by Kupsch et al., *EMBO J.*, 12(2): 641-650 (1993).

CONCLUSION

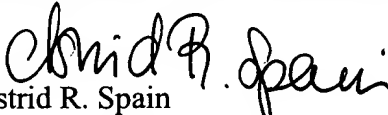
In light of the Amendments and Remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, he/she is invited to call the undersigned attorney.

Serial No.: 09/648,816

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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